Exhibit B

BEIJING BRUSSELS DUBAI FRANKFURT JOHANNESBURG LONDON LOS ANGELES NEW YORK PALO ALTO SAN FRANCISCO SEOUL SHANGHAI WASHINGTON Covington & Burling LLP One CityCenter 850 Tenth Street, NW Washington, DC 20001-4956 T +1 202 662 6000

By Electronic Mail

February 21, 2020

Mr. Michael B. Stuart United States Attorney Robert C. Byrd US Courthouse 300 Virginia Street Charleston, WV 25301 Email: mike.stuart@usdoj.gov

> Re: Touhy Requests in City of Huntington v. AmerisourceBergen Drug Corporation, 3:17-01362 (S.D. W. Va.), and Cabell County Commission v. AmerisourceBergen Drug Corporation, 3:17-01665 (S.D. W. Va.)

Dear Mr. Stuart:

I write on behalf of Defendants in the matters of *City of Huntington v. AmerisourceBergen Drug Corporation*, 3:17-01362, and *Cabell County Commission v. AmerisourceBergen Drug Corporation*, 3:17-01665, pending in the United States District Court for the Southern District of West Virginia. In connection with those lawsuits, we will subpoen documents and testimony from the Drug Enforcement Administration ("DEA"). Copies of the subpoenas and accompanying correspondence are attached for your reference as Exhibit 1 and Exhibit 2.

This letter is submitted pursuant to 28 C.F.R. § 16.21 *et seq.*, the Department of Justice *Touhy* regulations. Because these subpoenas are directed at DEA, compliance is subject to the *Touhy* process, and, for that reason, we have not effected formal service of process and hope that it will be unnecessary. The basis for this request is set forth below with reference to the requirements imposed by the *Touhy* regulations.

I. Summary of Information Sought and its Relevance to the Proceeding

These cases, recently remanded from *In re: National Prescription Opiate Litigation*, MDL No. 2804 (N.D. Ohio), involve claims by the City of Huntington and Cabell County Commission against DEA-registered pharmaceutical distributors. Plaintiffs allege, among other things, that the distributors violated the federal Controlled Substances Act ("CSA") and accompanying DEA regulations.

Given DEA's role in investigating and combatting prescription drug abuse in the Appalachian region, the discovery Defendants seek from DEA is crucial to Defendants' ability to defend against Plaintiffs' allegations. For example, discovery concerning DEA's investigation of

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unlawful diversion and communications regarding the source of any increase is crucial to responding to Plaintiffs' allegations regarding causation as well as assessing the reasonableness of Defendants' conduct. Likewise, discovery concerning DEA's use of suspicious order reports, ARCOS data, or any other communications from Defendants to combat the diversion or misuse of prescription opioids is critical to assessing the reasonableness of Defendants' conduct.

As summarized below, we request documents and testimony relating to Plaintiffs' allegations that Defendants violated duties arising under the CSA. Plaintiffs' allegations span a broad timeframe throughout which various DEA personnel interacted with Defendants and developed specialized knowledge of DEA practice and procedure.

A. Information Sought from DEA

Defendants request documents and testimony pursuant to Federal Rule of Civil Procedure 30(b)(6) from DEA relating, but not limited to, the following topics:

- Documents submitted by DEA to the House Energy and Commerce Committee as part of its investigation that resulted in the report *Red Flags and Warning Signs Ignored:*Opioid Distribution and Enforcement Concerns in West Virginia;
- The determination of estimates of diversion for Prescription Opioids during the Relevant Time Period pursuant to the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act);
- Efforts to utilize ARCOS data, suspicious order reports, or the West Virginia Controlled Substance Automated Prescription Program data to combat the diversion or misuse of Prescription Opioids in the City of Huntington, Cabell County, or any town, village, or city within Cabell County;
- The unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County;
- Any arrests, investigations, and indictments for crimes relating to the unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County;
- Efforts to combat the unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County;
- Individuals or entities suspected or known to have unlawfully produced, transported, diverted, sold, and/or trafficked Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County;

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- Efforts to suspend, revoke, or seek the suspension or revocation of registrations or licenses of, or fine or otherwise sanction any distributors, doctors, pharmacies, pharmacists, healthcare providers or other persons or entities because of the alleged diversion or trafficking of Prescription Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County;
- Recommendations for actions to be taken by DEA or any federal, state, or local agency
 within the City of Huntington, Cabell County, or any town, village, or city within Cabell
 County, to combat the use, misuse, abuse, sale, diversion, production, transportation,
 distribution, purchase, and/or trafficking of Prescription or Illicit Opioids;
- The structure and operation of the DEA within West Virginia, including but not limited to organizational charts and all Documents discussing the operation of DEA within West Virginia and DEA's staffing in West Virginia.
- The use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County;
- Efforts to combat drug-related crime, respond to the opioid epidemic, or form a joint task force to combat the opioid epidemic;
- The inspection, audit, or investigation conducted by DEA of any Defendant located in or distributing to pharmacies in West Virginia, including inspections, audits, and investigations that did not lead to any further investigation or enforcement action;
- DEA's policies and procedures and training with respect to inspections, audits and/or investigations of registrations in West Virginia, and summary information of completed inspections, audits and/or investigations of licensees by year;
- DEA's use of the Suspicious Order Reporting System (SORS), ARCOS data, or any other communications from Defendants to combat the diversion or misuse of Prescription Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County;
- DEA's policies and procedures and training with respect to inspections, audits and/or investigations of registrations in West Virginia, and summary information of completed inspections, audits and/or investigations of licensees by year;
- The investigation of suspicious orders reported by Defendants for West Virginia pharmacies, hospitals, or other dispensers for the Relevant Time Period;
- DEA's use of ARCOS data to investigate West Virginia pharmacies, pharmacists, or health care providers for the Relevant Time Period;

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- Any action DEA took in response to the U.S. Department of Justice Office of the Inspector General's report entitled *Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids* (September 2019);
- DEA's decision to establish only one Tactical Diversion Squad for West Virginia until 2016;
- The search and seizure warrant executed on Safescript Pharmacy #6 in the United States District Court for the Southern District of West Virginia, Huntington Division (3:12-mj-00010) (February 15, 2012):
- DEA's investigation of and decision to not prosecute Wendell Kent Freeman;
- Suspicious order reports for West Virginia pharmacies, hospitals, and other dispensers that were submitted directly to DEA field offices in West Virginia;
- DEA's efforts relating to diversion or misuse of prescription opioids in West Virginia;
- DEA's communications with any federal, state, or local agency regarding access to Suspicious Order Reporting System (SORs) and/or the ARCOS database;
- DEA's communications with or about the Healthcare Distribution Alliance (HDA) or Healthcare Distribution Management Association (HDMA);
- DEA's efforts to investigate any pharmacists, pharmacy interns, doctors or other prescribers in the City of Huntington, Cabell County, or any township, village, or city within Cabell County, prior to registering them or renewing their registration to lawfully prescribe or dispense controlled substances;
- The determination of Aggregate Production Quotas for Prescription Opioids;
- DEA's communications concerning Government Accountability Office (GAO) relating to the following report: *Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders*, GAO-20-118 (Washington, D.C.: January 2020); and
- DEA's instructions regarding the submission of suspicious order reports, including any and all Documents or Communications in which the DEA told a manufacturer or distributor to stop submitting suspicious order reports and/or excessive purchase reports.

II. Disclosure is Warranted Under 28 C.F.R. § 16.26

Pursuant to DOJ's *Touhy* regulations, the Deputy or Associate Attorney General assesses the following considerations in determining whether disclosure is warranted:

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- (1) Whether such disclosure is appropriate under the rules of procedure governing the case or matter in which the demand arose, and
- (2) Whether disclosure is appropriate under the relevant substantive law concerning privilege.

28 C.F.R. § 16.26(a).

This request satisfies both of these considerations. As explained previously, the requested documents and testimony directly concern the allegations in this lawsuit. Plaintiffs allege Distributors violated regulatory duties arising under the CSA, and the requested information is relevant to determining the nature of the alleged regulatory duties, the reasonableness of Defendants' conduct, and the role of Defendants in causing the injuries alleged by Plaintiffs. Moreover, Defendants do not request privileged documents.

Additionally, DOJ's *Touhy* regulations prohibit disclosure, subject to certain exceptions, if any of the following factors exist:

- (1) Disclosure would violate a statute, such as the income tax laws, 26 U.S.C. 6103 and 7213, or a rule of procedure, such as the grand jury secrecy rule, F.R.Cr.P., Rule 6(e),
- (2) Disclosure would violate a specific regulation;
- (3) Disclosure would reveal classified information, unless appropriately declassified by the originating agency,
- (4) Disclosure would reveal a confidential source or informant, unless the investigative agency and the source or informant have no objection,
- (5) Disclosure would reveal investigatory records compiled for law enforcement purposes, and would interfere with enforcement proceedings or disclose investigative techniques and procedures the effectiveness of which would thereby be impaired,
- (6) Disclosure would improperly reveal trade secrets without the owner's consent.

28 C.F.R. § 16.26(b).

This request is not intended to implicate any of these considerations. To the extent DOJ or DEA believe any of the requested information does implicate these considerations, Defendants are willing to work with DOJ, if possible, to narrow the scope of the request. The requested information is within the scope of ordinary subpoena practice and does not seek disclosure of information prohibited by statute or regulation, nor information that is classified

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or that would reveal the source of an informant. To the extent Defendants request investigatory records compiled for law enforcement purposes, Defendants do not request investigatory records that would interfere with ongoing enforcement proceedings. Further, in abundance of caution and to avoid any concern that disclosure of investigatory records would reveal "investigative techniques and procedures the effectiveness of which would thereby be impaired," Defendants request that the information be provided as highly confidential pursuant to the protective order governing this matter.

III. Expedited Response

We ask that you work with Defendants to establish a reasonable schedule for disclosure of the requested documents and completion of testimony prior to that date.

Please contact me directly at 202-662-5982 or lflahivewu@cov.com if you have any questions concerning this subpoena or require additional information.

Sincerely,

<u>/s/Laura Flahive Wu</u> Laura Flahive Wu

Counsel for Defendant McKesson Corporation

Attachments

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON,

Plaintiff,

v.

Civil Action No. 3:17-01362

AMERISOURCEBERGEN DRUG CORPORATION, et al.,

Defendants.

CABELL COUNTY COMMISSION,

Plaintiff,

 \mathbf{v}_{\bullet}

AMERISOURCEBERGEN DRUG CORPORATION, et al.,

Defendants.

Civil Action No. 3:17-01665

<u>DEFENDANTS' NOTICE OF SUBPOENAS FOR TESTIMONY AND PRODUCTION</u> OF DOCUMENTS TO THE U.S. DRUG ENFORCEMENT ADMINISTRATION

PLEASE TAKE NOTICE that, pursuant to Rules 30 and 45 of the Federal Rules of Civil Procedure, Defendants will serve the attached subpoenas commanding testimony and the production of documents on the U.S. Drug Enforcement Administration. The DEA shall produce the requested documents by March 12, 2020, at Covington & Burling LLP, One CityCenter, 850 Tenth Street, NW, Washington, DC 20001. The deposition will be held at Covington & Burling LLP, One CityCenter, 850 Tenth Street, NW, Washington, DC 20001 on a mutually agreeable date to be determined, and it will continue from day to day until completed. It will be taken

pursuant to the Federal Rules of Civil Procedure and other applicable laws for all lawful purposes, including trial. The deposition will be taken before a person authorized to administer oaths and will be recorded by videotape and stenographic means. You are invited to attend and participate.

Dated: February 21, 2020 Respectfully submitted,

BY: /s/ Laura Flahive Wu

Laura Flahive Wu COVINGTON & BURLING LLP One CityCenter 850 Tenth Street, NW Washington, DC 20001-4956 Telephone: (202) 662-5982 Iflahivewu@cov.com

Counsel for Defendant McKesson Corporation

/s/ Enu Mainigi

Enu Mainigi
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Washington, DC 20005
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Counsel for Defendant Cardinal Health, Inc.

/s/ Shannon E. McClure

Shannon E. McClure REED SMITH LLP Three Logan Square 1717 Arch Street, Suite 3100 Philadelphia, PA 19103 Telephone: (215) 851-8100 Fax: (215) 851-1420 smcclure@reedsmith.com

Counsel for Defendant

AmerisourceBergen Drug Corporation

CERTIFICATE OF SERVICE

I, Laura Flahive Wu, hereby certify that the foregoing document was served via email to all counsel of record.

/s/ Laura Flahive Wu LAURA FLAHIVE WU

Exhibit 1

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

United States District Court

for the

Southern District of West Virginia

City of Huntington; Cabell County Commission	
Plaintiff v. AmerisourceBergen Drug Corporation, et al.) Civil Action No. 3:17-01362; 3:17-01665
Defendant)
	MENTS, INFORMATION, OR OBJECTS OF PREMISES IN A CIVIL ACTION
To: U.S. Drug Enforcement Administration	, 8701 Morrissette Drive, Springfield, VA 22152
(Name of person to	whom this subpoena is directed)
Production: YOU ARE COMMANDED to production documents, electronically stored information, or objects, and material: See Schedule A	uce at the time, date, and place set forth below the following nd to permit inspection, copying, testing, or sampling of the
Place: Covington & Burling LLP	Date and Time:
850 10th Street NW Washington, DC 20001	03/12/2020 9:00 am
	ED to permit entry onto the designated premises, land, or date, and location set forth below, so that the requesting party the property or any designated object or operation on it. Date and Time:
	attached – Rule 45(c), relating to the place of compliance; to a subpoena; and Rule 45(e) and (g), relating to your duty to f not doing so.
Date:	
CLERK OF COURT	OR
Signature of Clerk or Deputy C	Clerk Attorney's signature
The name, address, e-mail address, and telephone number McKesson Corporation Jeff Wakefield, 200 Capitol Street, Charleston, WV 25301,	, who issues or requests this subpoena, are:

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action (Page 2)

Civil Action No. 3:17-01362; 3:17-01665

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

	ubpoena for (name of individual and title, if an	ny)	
late)	·		
☐ I served the s	subpoena by delivering a copy to the nar	med person as follows:	
		on (date) ;	or
☐ I returned the	e subpoena unexecuted because:	^^	
tendered to the v		States, or one of its officers or agents, I e, and the mileage allowed by law, in the	
iees are \$		for services, for a total of \$	0.00
I declare under p	penalty of perjury that this information i	is true.	
:			
		Server's signature	
		Printed name and title	

Additional information regarding attempted service, etc.:

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action(Page 3)

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

- (1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- **(B)** within the state where the person resides, is employed, or regularly transacts business in person, if the person
 - (i) is a party or a party's officer; or
- (ii) is commanded to attend a trial and would not incur substantial expense.

(2) For Other Discovery. A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
 - **(B)** inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

- (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
- **(B)** Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
- (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

- (A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
 - (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
 - (iv) subjects a person to undue burden.
- **(B)** When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
- (i) disclosing a trade secret or other confidential research, development, or commercial information; or

- (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
 - (ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

- (1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:
- (A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
- **(B)** Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
- (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.
- **(D)** Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
 - (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- **(B)** *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

Requests for Production of Documents to the Drug Enforcement Administration

DEFINITIONS

Notwithstanding any definition set forth below, each word, term, or phrase used in these Requests is intended to have the broadest meaning permitted under the Federal Rules of Civil Procedure and the Local Civil Rules for the U.S. District Court for the Southern District of West Virginia.

- 1. "You" and "Your" refers to the Drug Enforcement Administration ("DEA") and all others acting or purporting to act on DEA's behalf, including any employees, officers, committees, subcommittees, working groups, and joint task forces.
- 2. "Communication" means any transmission of information (whether formal or informal) by one or more Persons and/or between two or more Persons by means including, but not limited to, telephone conversations, letters, faxes, electronic mail, text messages, instant messages, other computer linkups, written memoranda, and face-to-face conversations.
- 3. "Defendants" means all defendants named in *The City of Huntington v. AmerisourceBergen Drug Corporation*, 3:17-01362 (S.D. W. Va.), or *Cabell County Commission v. AmerisourceBergen Drug Corporation*, 3:17-01665 (S.D. W. Va.), as of the date of this notice.
- 4. "Document" has the full meaning ascribed to it by Federal Rule of Civil Procedure 34(a), and means the complete original (or complete copy where the original is unavailable) and each non-identical copy (where different from the original because of notes made on the copy or otherwise) of any writing or record, including, but not limited to, all written, typewritten, handwritten, printed, or graphic matter of any kind or nature, however produced or reproduced, any form of collected data for use with electronic data processing equipment, and any mechanical or electronic visual or sound recordings or text messages in Your possession, custody, or control. "Documents" include, but are not limited to, books, papers, contracts, memoranda, invoices, correspondence, notes, studies, reports, manuals, photographs, drawings, charts, graphs, data compilations, other writings, microfilm, microfiche, audio recordings, video recordings, electronic mail, and any other information stored in electronic form, and each different version or copy of each Document, including, but not limited to, drafts.
- 5. "Prescription Opioids" means FDA-approved pain-reducing medications that consist of natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body to produce an analgesic effect, including but not limited to prescription medications containing hydrocodone, oxycodone, fentanyl, and hydromorphone, that may be obtained by patients in West Virginia only through prescriptions filled by dispensers duly licensed and regulated by DEA.

- 6. "Illicit Opioids" means substances comprised of or containing natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body that are not obtained from a licensed practitioner pursuant to a legitimate prescription. Illicit opioids include but are not limited to heroin, fentanyl, carfentanil, other fentanyl-type analogs, counterfeit opioid medications, and Prescription Opioids that are diverted.
- 7. "DEA Registrant" or "Registrant" means Registrant as defined in 21 C.F.R. § 1300.01(b) ("any person who is registered pursuant to either section 303 or section 1008 of the [Controlled Substances] Act").
- 8. "Registration" means Registration as defined in 21 C.F.R. § 1300.01(b) ("registration required and permitted by sections 303 or 1007 of the [Controlled Substances] Act").
- 9. "Aggregate Production Quota" means the quantity of Prescription Opioids "necessary to be manufactured during the following calendar year to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks" per 21 C.F.R. § 1303.11.
- 10. "Suspicious Order Monitoring Program" means a system intended to aid in compliance with 21 C.F.R. § 1301.74 as defined by DEA to be required by 21 C.F.R. § 1301.74.

INSTRUCTIONS

Should You consider any of the Documents requested to be confidential such that they should not be generally disseminated to the public or released to the press, we ask that You designate them as such under the Protective Orders in the MDL (copies attached) and the parties will deal with them accordingly.

To the extent You determine that any of the requests below implicate any type of law enforcement or investigative privilege, please identify which requests you believe implicate that privilege and please construe such requests to exclude Documents relating to current or ongoing investigations.

All of the following requests are intended to encompass Documents maintained in electronic or paper form, and "correspondence" or "Communications" include emails, letters or other papers, and memos reflecting oral Communications.

As these Documents will be shared with a large number of counsel and parties, we ask that You produce copies of them in electronic or paper form. Please let the undersigned know if there are charges or fees for searching or copying and, if so, also advise whether You will provide an invoice for the cost after production or if prepayment is required.

Unless otherwise indicated, the Relevant Time Period applicable to these requests is 1996 to the present.¹

DOCUMENTS TO BE PRODUCED

- 1. All Documents submitted by You to the House Energy and Commerce Committee as part of its investigation that resulted in the report *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, December 19, 2018, including but not limited to all Documents produced to the Committee, all written statements provided to Committee, and all notes, presentations, handouts and communications relating to the multiple briefings from DEA Staff to Committee Staff referenced in the Report.
- 2. All Documents and Communications concerning the determination of estimates of diversion for Prescription Opioids during the Relevant Time Period pursuant to the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), Pub. L. 115-271, 132 Stat. 3894. See https://www.deadiversion.usdoj.gov/fed_regs/quotas/2019/fr0912.htm.
- 3. All Documents describing, relating to, or reflecting efforts made by You to access or utilize ARCOS Data, Suspicious Order Reports, and/or West Virginia Controlled Substance Automated Prescription Program data to combat the diversion or misuse of Prescription Opioids in the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
- 4. All Documents referring or relating to the unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
- 5. All Documents and data referring, tracking, or relating to any arrests, investigations, and indictments for crimes relating to the unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
- 6. All Documents discussing, referring, or relating to Your efforts to combat the unlawful use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
- 7. All Documents and Communications identifying, discussing, or relating to the individuals or entities You suspect or know have unlawfully produced, transported, diverted, sold, and/or

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¹ Should the Court issue a ruling establishing a different time period for discovery, Defendants will revise the Relevant Time period accordingly.

- trafficked Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
- 8. All Documents referring or relating to Your efforts to suspend, revoke, or seek the suspension or revocation of registrations or licenses of, or fine or otherwise sanction any distributors, doctors, pharmacies, pharmacists, healthcare providers or other persons or entities because of the alleged diversion or trafficking of Prescription Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
- 9. All Documents that state, discuss, reflect, or suggest recommendations for actions to be taken by You or any federal, state, or local agency within the City of Huntington, Cabell County, or any town, village, or city within Cabell County, to combat the use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids.
- 10. Documents sufficient to show the structure and operation of the DEA within West Virginia, including but not limited to organizational charts and all Documents discussing the operation of DEA within West Virginia and DEA's staffing in West Virginia.
- 11. All Documents referring or relating to any Defendant regarding the use, misuse, abuse, sale, diversion, production, transportation, distribution, purchase, and/or trafficking of Prescription or Illicit Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
- 12. All Documents and Communications between You and any federal, state, or local agency (including but not limited to the West Virginia Board of Pharmacy, the West Virginia Board of Medicine, the West Virginia Board of Osteopathic Medicine, the West Virginia Board of Dentistry, the West Virginia State Board of Examiners for Licensed Practical Nurses, the West Virginia State Board of Examiners for Registered Professional Nurses, the Department of Justice, the FBI, other federal, state, and local law enforcement entities), and the City of Huntington, Cabell County, or any town, village, or city within Cabell County regarding Illicit Opioids, Prescription Opioids, diversion, or the opioid epidemic. Included within this response are all Documents and Communications regarding efforts to combat drug-related crime, respond to the opioid epidemic, or form a joint task force to combat the opioid epidemic.
- 13. All Documents reflecting or relating to any completed inspection, audit, or investigation conducted by You of any Defendant located in or distributing to pharmacies in West Virginia, including inspections, audits, and investigations that did not lead to any further investigation or enforcement action. Defendants can provide a list of registration numbers for the relevant distribution centers, if requested.
- 14. All Documents reflecting or relating to DEA's policies and procedures and training with respect to inspections, audits and/or investigations of registrations in West Virginia, and summary information of completed inspections, audits and/or investigations of licensees by year.

- 15. All Documents reflecting or relating to the DEA's policies, procedures, and training with respect to distribution or dispensing controlled substances for the treatment of pain.
- 16. All Communication between DEA Headquarters and DEA field offices related to Your use of the Suspicious Order Reporting System (SORS), ARCOS data, or any other communications from Defendants to combat the diversion or misuse of Prescription Opioids within or into the City of Huntington, Cabell County, or any town, village, or city within Cabell County.
- 17. All Documents relating to Your use of suspicious order reports submitted by Defendants to DEA Headquarters relating to West Virginia registrants, including but not limited to the transmittal of such suspicious order reports to DEA Diversion Investigators responsible for West Virginia and/or other federal, state or local government agencies.
- 18. All Documents related to any investigation of suspicious orders reported by Defendants for West Virginia pharmacies, hospitals, or other dispensers for the Relevant Time Period.
- 19. All Documents relating to Your use of ARCOS data or the West Virginia Controlled Substance Automated Prescription Program data to investigate West Virginia pharmacies, pharmacists, or health care providers for the Relevant Time Period.
- 20. All Documents and Communications relating to any proposed changes to 21 U.S.C. § 823, 21 C.F.R. § 1301.74, or any other DEA regulation and/or guidance with respect to suspicious orders for controlled substances, including but not limited to Your internal Communications and external Communications with registrants and the United States Congress.
- 21. All Documents and Communications relating to any action You took in response to the U.S. Department of Justice Office of the Inspector General's report entitled *Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids* (September 2019), including but not limited to internal communications relating to the recommendation that DEA "establish regulations, policies, and procedures that specifically define what constitutes a suspicious order, as well as what information should be included in a suspicious order report."
- 22. All Documents and Communications relating to DEA's decision to establish only one Tactical Diversion Squad for West Virginia until 2016.
- 23. All Documents arising out of the search and seizure warrant executed on Safescript Pharmacy #6 in the United States District Court for the Southern District of West Virginia, Huntington Division (3:12-mj-00010) (February 15, 2012).
- 24. All Documents relating to Your investigation of and decision to not prosecute Wendell Kent Freeman.
- 25. Documents sufficient to identify those individuals at DEA responsible for receiving, analyzing, and disseminating suspicious order reports submitted to DEA Headquarters relating to the distribution of Prescription Opioids to West Virginia pharmacies, hospitals, and other dispensers during the Relevant Time Period.

- 26. All Documents relating to suspicious order reports for West Virginia pharmacies, hospitals, and other dispensers that were submitted directly to DEA field offices in West Virginia during the Relevant Time Period, and all actions taken resulting from the same.
- 27. All DEA files and records relating to diversion or misuse of Prescription Opioids in West Virginia, including but not limited to correspondence or complaints related to potential or actual diversion or misuse of Prescription Opioids, documents and correspondence reflecting any actions undertaken by DEA relating to such complaints, and any other records relating to such complaints.
- 28. All Documents and Communications with any federal, state, or local agency in or with jurisdiction over the City of Huntington, Cabell County, or any township, village, or city within Cabell County, and/or any distributor or manufacturer, regarding access to Suspicious Order Reporting System (SORS) and/or the ARCOS database.
- 29. All Documents or Communications concerning the DEA's efforts to investigate any pharmacists, pharmacy interns, doctors or other prescribers in the City of Huntington, Cabell County, or any township, village, or city within Cabell County, prior to registering them or renewing their registration to lawfully prescribe or dispense controlled substances.
- 30. All Documents and Communications concerning the determination of Aggregate Production Quotas for Prescription Opioids during the Relevant Time Period.
- 31. All Documents concerning Communications with or about the Healthcare Distribution Alliance (HDA) or Healthcare Distribution Management Association (HDMA).
- 32. All Documents concerning Communications with or about the Government Accountability Office (GAO) relating to the following report: *Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders*, GAO-20-118 (Washington, D.C.: January 2020).
- 33. All Documents DEA has identified or determined were retained by Joseph Rannazzisi upon the conclusion of his employment with DEA, as well as all documents concerning DEA's investigation of whether documents were retained by Mr. Rannazzisi upon the conclusion of his employment with DEA.
- 34. The complete personnel file relating to the employment of Joseph Rannazzisi by the DEA.
- 35. All Documents provided by the DEA or by any current or former employee of the DEA to the Washington Post and/or to 60 Minutes, and all Documents concerning DEA's investigation relating to Documents provided to the Washington Post and/or 60 Minutes.
- 36. All Documents and Communications between DEA registrants and the Office of Diversion Control's Liaison and Policy Section relating to registrants' obligations under 21 C.F.R. § 1301.74.